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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,829	11/29/2001	Donald T. Shannon	VAS-5041CIP2	5289

7590 10/07/2003

Edwards Lifesciences LLC
Law Dept.
One Edwards Way
Irvine, CA 92614

EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,829	SHANNON, DONALD T.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *103-119* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *103-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: . .

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by its application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The declaration improperly refers to a non-related application (08/358350) and the correct application to which this application claims priority to has not been adequately identified. See MPEP § 601.01(a).

Specification

The disclosure is objected to because of the following informalities: on page 3, a subsection was numbered with (ii) and then on page 4 another subsection was numbered with (iv). What happened to (iii)? Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 111,112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 111 and 112 recite the limitation "the undulating elements" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claims. It appears the claims should depend from claim 109.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 103-105,107,113-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (5700285) in view of Choi et al. (4131648). Myers et al. disclose a stent (Fig. 1) having a plurality of lateral openings. Myers also discloses to place an outer tubular layer of at least one overlapping PTFE tape layer about the stent surface, col. 3, lines 56,57, col. 5, lines 35,44-49 and to sinter the tape, col. 5, lines 59-62. Regarding claim 113, Myers discloses a thickness for the tape less than 0.015 inches, col. 8, lines 3,4. With respect to claims 115,116, Myers also discloses a self-expanding stent, col. 3, lines 39,40 and a shape memory alloy, col. 4, lines 51-54. Regarding claim 117, Myers additionally discloses that PTFE layers can be placed in the stent as a base graft or luminal graft, col. 3, lines 56-59. However, Myers et al. fail to disclose a polymer incorporated with a therapeutic substance disposed on the surface of the stent. Choi et al. teach a polymer coating that is erodible and comprises a therapeutic agent, col. 2, lines 64-68. Choi also teaches that implantable tubular devices can be coated with the polymer, col. 28, lines 15-22. Choi additionally teaches that polymer is useful in aqueous environments, col. 28, lines 50-57,67,68. It would have been obvious to one of ordinary skill in the art to use the coating of a bioerodible polymer with a therapeutic agent as taught by Choi et al. on the surface of the stent of

Myers et al. such that a drug can be administered to the implantation site where trauma occurred, such as an anti-inflammatory, see col. 29 of Choi. With respect to claim 105, it should be noted that Choi et al. teach that erosion rates of the polymer can be at a rate of 1μ/hr (col. 36). It would have been an obvious matter of design choice to modify the erosion rate of the polymer, since applicant has not disclosed that using any specific erosion rate provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the erosion rate taught by Choi et al. or the claimed 2μ/hr in claim(s) 105 because both erosion rates for the polymers perform the same function of providing a controlled release rate of the therapeutic agent.

Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 103 above, and further in view of Michal et al. (6287285). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to disclose the drug paclitaxel to be used on the stent. Michal et al. teach therapeutic agents, such as paclitaxel are used in the invention, col. 4, lines 1,2,9. Michal also teaches that the coating with the drug can be on a metal stent surface, col. 5, lines 34-44. It would have been obvious to one of ordinary skill in the art to use the drug paclitaxel as taught by Michal et al. in the stent of Myers et al. as modified by Choi et al. in order to reduce restenosis.

Claims 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 103 above, and further in

view of Wijay (6053940). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to disclose a non-foreshortening stent. Wijay teaches a stent having a plurality of undulating elements with at least one linear connector, Fig. 1. Wijay also teaches that the design of the stent allows the length to remain substantially constant in the deployed state, col. 9, lines 48-55. It would have been obvious to one of ordinary skill in the art to use the stent design as taught by Wijay in the stent of Myers et al. as modified by Choi et al. in order to provide the maximum support to the vessel and reduce twisting and unwanted turbulence of blood flow.

Claims 108-110,112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 103 above, and further in view of Becker (6117165). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to disclose a non-foreshortening stent. Becker teaches a stent having a plurality of undulating elements with at least one connector, Fig. 6. Becker also teaches that the design of the stent allows the length to remain substantially constant in the deployed state, col. 4, lines 1-10. It would have been obvious to one of ordinary skill in the art to use the stent design as taught by Becker in the stent of Myers et al. as modified by Choi et al. in order to provide the maximum support to the vessel and increasing the effective range of the stent.

Claims 118,119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 117 above, and further in view of Banas et al. (5749880). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to PTFE particles used to bond the tubular inner and

outer layers. Banas et al teach an aqueous polymer solution of PTFE between the inner graft and outer graft layer to bond the layers, col. 10, lines 4-8. Bans also teaches the outer tubular layer is heated to bond to the base, col. 20, lines 41-45. It would have been obvious to one of ordinary skill in the art to substitute the adhesive material and use PTFE particles (in solution) as taught by Banas in the stent of Myers et al. as modified by Choi et al. in order to provide a good bond so the layers do not separate in the vessel. Using like materials enhances the bond as opposed to the adhesive material used by Myers using dissimilar material to bond the layers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino

TC 3700, AU 3738

Brian Pellegrino